REMARKS

Pending claims

Claims 1-20 were originally filed in this application. By this Amendment, claims 1-20 have been cancelled and substituted with new claims 21-36. New claim 21 basically corresponds to originally filed claims 1 and 2. New claim 22 is directed to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:4. New claim 23 basically corresponds to originally filed claim 3. New claim 24 is directed to an isolated polynucleotide encoding the amino acid sequence of SEQ ID NO:4 (it is submitted that this claim falls within the election of the Restriction Requirement and contains the elected SEQ ID NO). New claim 25 basically corresponds to originally filed claim 12 (it is submitted that this claim falls within the election of the Restriction Requirement and contains the elected SEQ ID NO). New claims 26 and 28 basically correspond to originally filed claims 13 and 14, respectively (it is submitted that these claims fall within the election of the Restriction Requirement and contain the elected SEQ ID NO). New claim 27 is directed to a transgenic organism comprising the recombinant polynucleotide of claim 25. New claim 29 basically corresponds to originally filed claim 16. New claim 30 basically corresponds to originally filed claims 9, 10 and 11 (it is submitted that this claim falls within the election of the Restriction Requirement). New claim 31 basically corresponds to originally filed claims 9, 10 and 11 but is directed to SEQ ID NO:9 (it is submitted that this claim falls within the election of the Restriction Requirement and contains the elected SEQ ID NO). New claims 32, 33 and 34 basically correspond to originally filed claim 7 but are directed to SEQ ID NO:9. New claim 35 basically corresponds to originally filed claim 15. New claim 36 basically corresponds to originally filed claim 19.

Please note that the originally filed claims directed to the agonist, antagonist and methods using the claimed agonist or antagonist are not contained in the set of new claims. Applicants expressly state that these claims are not being pursued in order to expedite prosecution of the new claims and **not** for reasons related to patentability, and are in fact fully supported by the specification as filed. Applicants expressly reserve the right to reinstate these claims or to add other claims during prosecution of this application or a continuation or divisional application. Applicants expressly do not disclaim the subject matter of any invention disclosed herein which is not set forth in the instantly filed new claims.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 1, 2, and 15) drawn to a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ iD NO:1-5 and fragments thereof.

Group II (claims 3-6 and 9-11, 12-14) drawn to a polynucleotide encoding the polypeptide of claim 1 and vectors and host cells expressing said polynucleotide and methods of expressing said polynucleotide.

Group III (claims 7 and 8) drawn to a method for detecting a polynucleotide.

Group IV (claim 16) drawn to an antibody that specifically binds to the polypeptide of claim 1.

Group V (claim 17) drawn to an agonist of the polypeptide of claim 1.

Group VI (claim 18) drawn to an antagonist of the polypeptide of claim 1.

Group VII (claim 19) drawn to a method for treating a disorder associated with decreased expression of a CoA enzyme comprising administering the polypeptide of claim 1.

Group VIII (claim 20) drawn to a method for treating a disorder associated with decreased expression of a CoA enzyme comprising administering the antagonist of claim 18.

Applicants hereby elect, with traverse, to prosecute Group II, which includes and is drawn to at least new claims 23-26, 28, 30 and 31. Applicants reserve the right to prosecute the subject matter of nonelected claims in subsequent divisional applications.

In the Restriction Requirement, the Examiner further requested Applicants to elect a single SEQ ID NO.

Applicants hereby elect, with traverse, to prosecute SEQ ID NO:9, which includes and is drawn to at least new claims 24-26, 28 and 31. Applicants reserve the right to prosecute the subject matter of nonelected SEQ ID NOs in subsequent divisional applications.

Applicants traverse this Restriction Requirement on several grounds.

First, Applicants traverse the Restriction Requirement as between the claims of Groups II and Group VII (i.e., new claims 32-34, drawn to methods of detecting a target polynucleotide having a sequence of a polynucleotide of claim 31). The method claims are directed to a method which depends on knowing the sequence of the polynucleotide of claim 31. Therefore, a search of the claimed polynucleotides would substantially overlap examination of method claims 32-34 and would not be an undue burden on the Examiner.

Second, Applicants traverse the Restriction Requirement as between the claims of Groups II and I (drawn to polypeptides related to SEQ ID NO:4). Many of the elected claims of Group II are directed specifically to polynucleotides encoding the claimed polypeptides, and thus it is presumed that a proper search for the claimed polynucleotides would include the polypeptides which they encode. Therefore, it is submitted that it would not be a substantial burden on the Examiner to use the results of the necessary polynucleotide search to examine the polypeptide claims.

Third, Applicants traverse the Restriction Requirement as between the Group I and Group IV (drawn to the polypeptides and antibodies to the polypeptide, respectively), and hence Group II. The claims of these groups could be examined at the same time, also without an undue burden on the Examiner. A search of the prior art to determine the novelty of the antibodies would substantially overlap with a search of the claims directed to the polypeptides. Thus, Applicants submit that examining the prior art for the polypeptides together with the antibodies would involve substantially the same subject matter and would not impose an undue burden on the Examiner.

Accordingly, as submitted above, a search of the claimed polynucleotides would include the claimed encoded polypeptides. Therefore, it is submitted that it would not be a substantial burden on the Examiner to use the results of the necessary polynucleotide search to examine the polypeptide together with the antibody claims.

In support of this second ground is the attached Fujino, T. et al. article and the attached Minekura, H. et al article. The Fujino, T. et al. article discloses the rat Acyl-CoA synthetase 3 cDNA and protein (GI 1468969), a very similar polynucleotide (GI 1468968), a very similar polypeptide encoded by this very similar polynucleotide, and the expression of this very similar polypeptide. The Minekura, H. et al. article also discloses a very similar human polynucleotide (GI 1465017), a very

similar human polypeptide (GI4165018) encoded by this very similar polynucleotide, and the mapping of this very similar polynucleotide to 2q34-q35. Additionally, alignments of SEQ ID NO:4 to very similar human polypeptides (Exhibit A) and alignments of SEQ ID NO:9 to the very similar human polynucleotide sequences (Exhibit B) and the rat polypeptide homolog (GI 1468969) along with the very similar human polypeptide sequences (Exhibit C) are also enclosed. Accordingly, these articles demonstrate that examining the prior art for the polynucleotides together with the polypeptides would involve substantially the same subject matter/sources and would not impose an undue burden on the Examiner.

In addition, Applicants submit that claim 27, drawn to a transgenic organism comprising the recombinant polynucleotide of claim 25 belongs within elected the claims of Groups II. This claim is directed to a product that contains the claimed recombinant polynucleotide of claim 25 to be searched by the Examiner. Therefore, a search of the claimed recombinant polynucleotide of claim 25 would substantially overlap examination of a transgenic organism of claim 27 and would not be an undue burden on the Examiner.

Applicants further traverse on the grounds that the Examiner should also examine new claims 23 and 30, drawn specifically to polynucleotides encoding the polypeptides related to the amino acid sequences of SEQ ID NOs:1-3 and 5 (of which polynucleotides sequences of SEQ ID NOs:6-8 and 10 are included, respectively). These claims are written so that the sequences are part of a Markush group. Applicants submit that these Markush groups are proper. M.P.E.P § 803.02, reproduced below in its entirety, with relevant portions highlighted:

PRACTICE RE MARKUSH-TYPE CLAIMS

> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. ***In such a case, the examiner will not follow the procedure described below and will not require restriction.***

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.**

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent

> necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

First and foremost, if the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. **In such a case, the examiner will not follow the procedure described below and will not require restriction.**" Withdrawal of the restriction requirement as between the **five** (5) specific sequences each in the claims is required on that basis alone.

Second, "**it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention . . . Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.**" Clearly, the five polynucleotides of the instant invention, and polypeptide sequences encoding by them, share both a common utility and structural homology, based on their classification as human Coenzyme A-utilizing enzymes.

Third, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," it is further noted that the M.P.E.P states that "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, "**the examiner may require a provisional election of a single species** prior to examination on the merits" but if no prior art is found, examination must continue on the other claimed species. This clearly applies in the present case.

Therefore, it is respectfully submitted that, upon searching and examining polynucleotides encoding the polypeptides relating to SEQ ID NO:4 and finding no prior art over which they can be

rejected, the Examiner **must** extend the search of the Markush-type claim to include the nonelected species.

Rejoinder

Applicants traverse on the grounds that the Examiner could also examine new claims 32-34, drawn to methods of detecting a target polynucleotide having a sequence of a polynucleotide of claim 31. The Examiner's attention is directed to the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for the rejoinder of process claims covering the same scope of products. Therefore, upon allowance of any of the claims within Group II, *i.e.*, new claims 24-26, 28 and 31, the new method claims 32-34, which depend therefrom, should be rejoined and examined.

Please charge Deposit Account No. **09-0108** in the amount of **$110.00** as set forth in the enclosed fee transmittal letter. If the USPTO determines that an additional fee is necessary, please charge any required fee to Deposit Account No. **09-0108.**

Respectfully submitted,

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Attachments: Fujino, T. et al., *JBC*, 271(28):16748-16752 (1996)
Minekura, H. et al., *Genomics*, 42:180-181 (1997)
Exhibit A: Sequence alignment, SEQ ID NO:4 to A CoA-3, polypeptide
Exhibit B: Sequence alignment, SEQ ID NO:9 to A CoA-3, polynucleotide
Exhibit C: Sequence alignment, SEQ ID NO:4 to A CoA-3, polypeptide from rat